

to the restriction requirement on November 1, 2002, Paper No. 5 (copy attached), traversing the requirement and electing a species.

In the January 17, 2003 Office Communication, claims 31 and 32 were rejoined with the Group I claims. Claims 33 and 34 were withdrawn from consideration as being drawn to a nonelected invention, and the Examiner acknowledged that Applicant timely traversed the restriction (election) requirement in Paper No. 5.

However, the Examiner stated:

“Applicants’ traversal (Paper No. 5, pages 2-3) of the requirement for restriction is improper is not persuasive (sic).”

No basis or other explanation was offered as to why Applicants’ traversal of the restriction requirement was “improper.” Applicants maintain that the traversal was proper, and assume that the statement that the traversal was improper was a typographical error because the Examiner provided no basis for the assertion that the traversal was improper.

Although the Examiner did not expressly state that the restriction requirement “is still deemed proper and is therefore made FINAL”, as Section 821.01 of the Manual of Patent Examining Procedure (MPEP) instructs, the Examiner withdrew the nonelected claims from consideration, and searched and examined only a single marker sequence and a single primer pair. Thus, Applicants assert that the Examiner’s treatment of the claims constitutes “a final requirement for restriction” under 37 C.F. R. 1.144 and, therefore, Applicants herein petition the Commissioner to review the requirement.

Applicants petition the Commissioner to review the Examiner’s requirement that Applicants select a single marker sequence and a pair of primer sequences to be searched. Applicants respectfully request that the Examiner be directed to search the ten marker sequences recited in the claims as filed in a single application.

In the January 17, 2003 Office Communication, the Examiner responded to the Applicants’ traversal as follows:

*Applicants argue that ten independent and distinct nucleotide sequences (along with one pair of primers for each of the distinct nucleotide sequences) should be examined on the merits as outlined in Examination of Patent Applications Containing Nucleotide Sequences, 1192 OG 68 (November 19, 1996) and MPEP 803.04. At the time of the O.G. notice, the size of nucleotide sequence databases was considerably smaller than it is now. For example, in 1996, GenBank® contained about  $6.52 \times 10^8$  nucleotides in its main database, while in 2001 the same database*

*contained about  $1.58 \times 10^{10}$  nucleotides. This represents a 25-fold increase in GenBank®, which continues to double about every 14 months (figures from <http://www.ncbi.nlm.nih.gov/Genbank/genbankstats.html>). The increasing size of this and other sequence databases no longer makes it practicable to search more than one unrelated nucleotide sequence in a single application. Accordingly only SEQ ID NO:32 and its primer pair of SEQ ID NOs:124-125 as selected by applicants in paper no. 5 have been examined on the merits. (emphasis supplied)*

Applicants' representative, Attorney Jill A. Fahrlander, telephoned Examiner Martinell on February 11, 2003 to discuss with him his position regarding searching and examining only a single sequence. Examiner Martinell informed Attorney Fahrlander that it is now the practice of their Group Art Unit to search only a single sequence. On March 31, 2003, Attorney Fahrlander telephoned Supervisor Michael Woodward to discuss the restriction and species election requirement. Supervisor Woodward echoed Examiner Martinell's characterization of the restriction practice in applications including sequences, stating that it has been in effect for two years. Neither Examiner Martinell nor Supervisor Woodward cited any authority for failing to follow MPEP §803.04. Further, no other MPEP section or other authority was cited for this dramatic change in examination policy.

Applicants respectfully submit that this unofficial policy adopted by this Group Art Unit is grossly unfair to Applicants. This wholesale change in restriction practice *vis á vis* sequences potentially represents a ten-fold increase in costs associated with patent procurement and maintenance that disproportionately affects those in a particular technology viz., the biotechnology industry. Despite the tremendous impact that this change in policy has on the biotechnology industry, the change was made without public notice and without opportunity for public comment.

The secrecy associated with adopting and implementing what effectively represents a new tax levied against one particular group of USPTO customers has the effect of undermining efforts by Applicants and others in the industry to plan and budget for expenses associated with patent procurement. A 1000% increase in patent procurement expenses is hardly a trivial matter. The USPTO owes it to its customers to provide notice concerning the adoption of policies that are likely to affect the customers' economic interests and to permit public comment relating thereto.


Furthermore, the adoption of this policy behind closed doors makes it difficult for Applicants and others to respond to the USPTO's rationale for implementing this new restriction practice. Absent any publicly available information to the contrary, Applicants can only assume that the USPTO's rationale is represented by the Examiner's comments regarding the effect of the increase in the number of sequences in GenBank® and other databases on the USPTO's ability to search more than one sequence per application. The Examiner's position that an increase in the size of the databases makes it unduly burdensome to search more than one sequence per application is untenable. Applicants acknowledge that there has undoubtedly been an increase in the size of the relevant databases since the publication of in *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 OG 68 (November 19, 1996) and its subsequent incorporation into the MPEP at Section 803.04. However, Applicants submit that the speed and capacity of computers and sequence analysis software has increased at a far greater rate over the relevant time frame. Input from experts in the field would allow the USPTO and the public to obtain a more balanced and accurate picture of the actual effect that increases in database sizes may or may not have on conducting searches.

In the interest of fairness, Applicants respectfully request that the Commissioner reconsider the restriction requirement and direct the Examiner to search the full scope of the elected Group I claims.

This petition is accompanied by check number 47313 in the amount of \$240.00 to cover the fees required under 37 C.F.R. 1.17(a)(1), 37 C.F.R. 1.144 and 37 C.F.R. 1.181. No other fee is believed due in connection with submission. However, if any fee is owing, please charge such fee to Deposit Account No. 50-0842.

Respectfully submitted,

Date: May 19, 2003

  
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